

SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 8TH OCTOBER 2024

Information is being withheld, under Section 43 of the Freedom of Information Act 2000, on the grounds that information regarding the issue under consideration and advice from the IDWG remains confidential at the date of this summary and will remain so until a final decision has been taken. Any request for future information should be made direct to the MHRA (via info@mhra.gov.uk) and will be considered in accordance with the FOI Act.

Papers for advice/discussion

The IDWG were presented with an overview of exceptional use authorisations (EUA). The presentation covered the background for EUA applications, internal processes for managing EUAs within the Agency and observed trends.

The IDWG were presented with a summary of the benefit risk evaluation concerning a device used for feeding tube guidance, when placing nasogastric feeding tubes. The IDWG agreed with the proposals made by the MHRA on this item, including that this topic was returned to IDWG in future when further assessment of the issue had been undertaken.

The IDWG were given a high-level overview of signals assessed by the MHRA in August. The signal concerned an update 0.9% Sodium chloride irrigation solution, 0.9% Sodium chloride inhalation solution and Aero wash eyewash and Ralstonia pickettii outbreak. The MHRA agreed to ask Legacy Remedies Private Ltd to provide further reconciliation data from their supplier. The MHRA is considering formally suspending the device from the UK market. The IDWG had no further questions or comments.

Matters arising

The IDWG were presented with a status update regarding the rectopexy mesh review.

The IDWG was provided with an update concerning an investigation into a defibrillator.

Agency device related internal updates

The MHRA informed the IDWG of a Regulation 28 Prevention of Future Deaths report received from the Surrey Coroner's office. An inquest into a death which had occurred at a care home in June 2023 had found that the bed with an extension had been assembled incorrectly, with the base (or deck) of the extension missing. This meant that the mattress extension was not supported properly, and the patient fell through the gap and became trapped. The patient subsequently died due to positional asphyxia and bronchopneumonia. The coroner was concerned that there was a lack of awareness on the need to ensure appropriate support for the mattress extension when using a bed with an extension, and also that there was a lack of awareness that there was a potential risk of death.

The MHRA reviewed the user manual for the bed, and found that there were clear instructions on how to assemble the bed, including diagrams showing the deck. There was also a general warning on the risk of entrapment leading to asphyxiation and death. The user manual also contained requirements for regular servicing, which includes a physical inspection, and that this should be conducted by appropriately trained personnel only.

Neither the MHRA nor the manufacturer had received any similar reports of entrapment due to a missing extension deck, although the issue of entrapment with beds and bed rails is well known. The MHRA issued a National Patient Safety Alert in August 2023 warning of the risk of death from entrapment and falls with medical beds, bed rails, bed grab handles and lateral turning devices. This Alert requires that relevant staff receive device training suitable to their roles, organisations have an up-to-date medical device management system in place, and that regular servicing and maintenance of these medical devices is implemented in line with the manufacturer's instructions.

It also requires regular risk assessments for patients using bed rails or handles, including entrapment risks.

The MHRA has discussed with the National Association of Medical Device Educators and Trainers (NAMDET) the possibility of producing training materials for users of beds and bed rails, and the risks relating to entrapment, and this is currently being drafted, with a view to be available in the coming months.

The MHRA is not planning on taking any further actions, although we are continuing to actively monitor incidents involving entrapment with beds and associated devices, and will take further action if any adverse signals are found.

The IDWG were notified of the intention for the MHRA to scope out a review of the MHRA guidance and advice on metal on metal hip replacements to determine if updates are required. The IDWG supported the MHRA's intention.

The IDWG were advised that the MHRA is awaiting further evidence and case details from a journalist regarding an article about certain hip replacement devices. The IDWG were informed that the MHRA plans to review the evidence to determine if any further action is needed.

The IDWG was provided with an update regarding an ongoing field safety notice concerning the recall of tracheostomy tubes due to a manufacturing defect.

The IWD was updated on the work undertaken by the Open Oximetry Collaborative Community (of which MHRA is a member) on a draft infographic produced about pulse oximetry intended for healthcare professionals.

Procedural Items

In addition, the Group completed its usual procedural business including the need to observe the confidentiality of the meeting, to declare interests, apologies, announcements, approval of minutes, and updates on items previously considered. No interests were declared.

A list of members who participated in the meeting is at **Annex A**.

Medicines Healthcare products Regulatory Agency staff may be present for all or part of the meetings or for specific items.

The meeting started at 10:03 and finished at 12:26.

The next meeting is scheduled to take place on 12th November 2024 at 10:00.

Useful website links

MHRA Website:

[Medicines and Healthcare products Regulatory Agency - GOV.UK \(www.gov.uk\)](https://www.gov.uk)

MHRA Alerts, recalls and safety information:

[Alerts, recalls and safety information: drugs and medical devices - GOV.UK \(www.gov.uk\)](https://www.gov.uk)

Yellow Card Website:

[Yellow Card Scheme - MHRA](https://www.mhra.gov.uk)

Drug Safety Update:

<http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/index.htm>

MEMBERSHIP OF THE INTERIM DEVICES WORKING GROUP

Post	Name and title	Affiliations
Chair	Professor Tom Clutton-Brock MBE MB ChB FRCP FRCA FFICM	Director, Medical Devices Testing and Evaluation Centre, Clinical Director, NIHR HealthTech Research Centre in Devices, digital and robotics (HRC-DDR), Chair, NICE Interventional Procedures Advisory Committee, Associate Medical Director, University Hospitals Birmingham NHS Foundation Trust, Professor of Anaesthesia & Intensive Care Medicine, University of Birmingham
Member	Mr Jonathan Boyle MB ChB MD MA (Cantab) FRCSEd FRCSEng FRCS (Gen.Surg)	Consultant Vascular Surgeon and affiliate Assistant Professor, Cambridge University Hospitals NHS Trust, University Hospital Southampton
Member	Professor Richard Bulbulia MA MD FRCS FRCS(Gen)	Associate Professor, Clinical Trial Service Unit and Epidemiological Studies Unit, Nuffield Department of Population Health, University of Oxford; Medical Research Council Population Health Research Unit at the University of Oxford; Honorary Consultant Vascular Surgeon, Gloucestershire Hospitals NHS Foundation Trust
Member	Professor Alastair Denniston MA MRCP FRCOphth PhD	Consultant Ophthalmologist (Uveitis and Medical Retina), University Hospitals Birmingham NHSFT, Honorary Professor and Deputy Director Centre for Regulatory Science and Innovation, University of Birmingham
Lay Member	Dr Rebecca Harmston	
Member	Mr Michael Hart BSc (Hons) MBChB AHEA PhD FRCSEd (Neuro.surg) FEBNS	Senior Lecturer & Honorary Consultant Neurosurgeon, St George's, University of London & St George's University Hospitals NHS Foundation Trust
Member	Professor Chris Hopkins BSc (Hons) FAHCS FIPEM CEng MIET (<i>apologies</i>)	Consultant Clinical Scientist, Honorary Professor and Clinical Director, Assistive Technologies Innovation Centre, University of Wales Trinity Saint David, Head of the Tritech Institute, Hywel Dda University Health Board, Assistant Director of Health Science and AHP's, Betsi Cadwaladr University Health Board
Member	Mr Sebastian Janner MSci MSc	Clinical Scientist, Royal Brompton and Harefield Hospitals
Member	Professor Tom Joyce PhD MSc BEng	Professor of Orthopaedic Engineering, Newcastle University
Member	Professor Daniel Martin OBE BSc MB ChB PhD FRCA FFICM	Professor of Perioperative and Intensive Care Medicine, Peninsula Medical School, University of Plymouth

Post	Name and title	Affiliations
Member	Dr Rubeta Matin PhD BSc (Hons) MBBS FRCP(Derm) <i>(apologies)</i>	Consultant Dermatologist, Oxford University Hospitals NHS Foundation Trust; Honorary Senior Clinical Lecturer, University of Oxford
Member	Dr Tom Pelly MBBS BSc (Hons) DCH PGCE FRCP FRCGP	GP Partner, Horfield Health Centre, Bristol; Clinical Director, Phoenix Primary Care Network, Bristol; RCGP Representative
Member	Professor Muireann Quigley BSc (Med) BSc (Hons) MBChB MA PhD <i>(apologies)</i>	Chair in Law, Medicine, and Technology, Birmingham Law School, University of Birmingham
Member	Dr Neil Smart BSc (Hons) MBChB FCAI MBA	Chair of the Scottish Health Technologies Group, Consultant Anaesthetist NHS Greater Glasgow and Clyde and Honorary Clinical Senior Lecturer, University of Glasgow
Lay Member	Ms Josephine Tapper	
Observer	Peter Barry	Consultant Clinical Advisor, Centre for Guidelines, National Institute for Health and Care Excellence
Observer	Sarah Jennings	Patient Safety Clinical Lead - Medical Devices, NHS England
Observer	Iain Robertson	Medical Advisor Medical Devices and Legislation Unit, Scottish Government